ORGAN DONATION AND TRANSPLANT TOURISM- A LEGAL PERSPECTIVE

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Introduction

Recent medical development and techniques have promised and brought hope for many patients with organ failure. Chronically ill patients have improved longevity and quality of life by radical surgical intervention wherein parts in one individual are used to replace dysfunctional ones in the others. Such surgeries are called organ transplantation surgeries. Medical science has been revolutionized by formulating successful surgeries for the transplantation of various organs and development of artificial organs, stem cell research, xenotransplantation and anti-rejection drugs which play a major role in increasing the success rate of transplantation procedures. Organ donation is the donation of biological tissue or an organ of the human body from a living or dead person to a living recipient in need of a transplantation. An organ donor can save up to eight lives and save or improve the lives of over a hundred people.314 Organ donation exemplifies ‘Charity across life’. Organ donation impacts a staggering number of people and the stories of how organ transplantation has affected someone’s life are often collected to be shared with others.315 Although success of organ transplants reflects advances in medical procedures, the success has generated debates about the ethical standards and policies that govern transplants, especially the acquisition of organs for transplants.316

Organ donors provide the recipients a second chance at life. Any person irrespective of age, gender, caste, creed, religion, race and community can be an organ donor. A few medical conditions may deny a person from becoming a donor however such persons might still be able to donate a few parts of his or her body under doctor’s guidance and advice. Organ donation has been evidence of humanitarianism, generosity and altruism. Organs that can be transplanted are the heart, kidneys, liver, lungs, pancreas, intestine and thymus. Many tissues, bones, cornea, skin, heart valves, nerves and veins can also be transplanted. Organs used for transplantation

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315 Ethics of Organ Transplantation, Centre for Bioethics February 2004
can be from a living person or a cadaver. Organs procured from deceased people are called cadaveric organs. Living persons can also donate organs from their paired organ set (like a kidney) or a portion of their organ without which they will be able to function (like a liver). The “standard position” on organ donation is that the donor must be dead in order for vital organs to be removed. The ethics of organ transplantation have been premised on “the dead-donor rule” (DDR), which states that vital organs should be taken only from persons who are dead. Allegiance to the dead donor rule limits the procurement of transplantable organs by denying some patients the option to donate in situations in which death is imminent and donation is desired like in the case of brain death. Many reported cases of accidental deaths and suicides result in brain death. Brain-dead patients are permanently unconscious and cannot live without a ventilator support and thus recovery of their organs is considered acceptable if organ donation is desired by the patient or by the surrogate on the patient's behalf.

The Cadaver kidney transplantation in India was first undertaken in 1965 in Mumbai and the members of medical profession had to face several medical and social problems such as difficulties in engrafting, immunological problems and infections. The whole-process was described as neo-cannibalism and this created a setback in cadaver transplantation not only in Mumbai but also in rest of the parts of the Country. However, the position has now slightly changed to the better because of the scientific advancements and formulation of legal regulations in the Country. Organ donation has still not attained complete acceptance from the common man because of misconceptions and inaccuracies. People are restricted by the cultural and religious ties they have to their body after death. However, most major religions in the world support organ donation. It is seen as an ultimate act of philanthropy and generosity. The body is treated with care during the entire transplantation process and thus can be disposed with dignity and respect after the transplantation procedures.

Organ Donation in India: Legal Perspective

317 M. Potts D W Evans, Does it matter that organ donors are not dead? Ethical and policy implications, Journal of Med Ethics 2005; 31:406-409
In India, the law regulating the transplantation of human organs is the Transplantation of Human Organs Act (THOA), 1994 and its allied rules. However, even before its enactment certain states like Maharashtra had similar Acts to govern organ transplantation. The Act was mainly passed to curtail the commercial dealing in human organs as a number of scandals involving medical practitioners and the illegal organ trading in the red market came to limelight. The main object of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes, the prevention of commercial dealings in human organs and for matters connected therewith. The conventional definition of ‘death’ has also been modified to include ‘brain stem death’. The determination of brain death has assumed importance for two main reasons; firstly, the ability to support vegetative functions for prolonged periods after brain death and Secondly, the need for organs for transplantation.

The main provisions of the THOA, 1994 is as follows:

a) The live donor must give his consent in writing, in the presence of two or more witnesses and one such witness should be his near relative (at the time of his death) for the removal of organs from his body after death.
b) The authorised age for organ donation is 18 years and in case of minors, the parents can give consent to donate organs.
c) Where a body is unclaimed in the hospital for more than forty eight hours, the person in charge of the hospital can authorise for the removal of organs from such bodies.
d) In cases of medico-legal cases or when body sent for post-mortem for pathological purposes, a competent doctor can authorise for the removal of organs only if it is believed that such human organ is not required for the purpose for which the body has been sent for post-mortem examination. Further, the deceased person should not have expressly objected for removal of organs on the occurrence of his death.
e) The organs of the donor can be transplanted only to a recipient who is a near relative of the donor. In cases of unrelated donors, the organ can be transplanted to the body of any recipient, provided the prior approval of the Authorisation Committee has been obtained.

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320 Kuldeep Singh v. State of Tamil Nadu [AIR 2005 SC 2106]
321 Section 2(p) of THOA defines “Transplantation” as means of grafting any human organs from any living person or deceased person to some other living person for any therapeutic purposes.
f) The hospitals which are engaged in removal, storage and transplantation of human organs must be registered and if they violate any condition, the registration may be cancelled after due enquiry.

g) Any person or hospital involved in the removal of any human organ without authority shall be punished with imprisonment up to five years and a fine up to ten thousand rupees.

h) If a medical practitioner is involved in commercial or illegal trade of human organs and convicted thereof, his name may be removed from the medical register for a period of two years for the first offence and removed permanently for the subsequent offence.

i) The punishment for commercial dealing in human organs is imprisonment for not less than two years which may extend to seven years and also a fine of not less than ten thousand rupees which may extend to twenty thousand rupees.

j) A recent amendment of the Act in 2011, and of the Rules in 2014, have created a category of institutions called "non-transplant organ retrieval centres" where organs can be retrieved after consent and then transported to an institution where the recipient procedure is to be performed.

The commercial dealing of human organs and their illegal trading is a matter of serious concern in the current scenario. The Act provides for setting up of Authorisation Committees and also Appropriate Authority at the State levels to regulate hospitals registered to deal with human organ transplantation. Yet the legislation has not achieved its purpose in the long run and it is pertinent to note that such activities occurred even after the Act has come into force. The lacunae in the law have been a main reason for such illegal activities. In a study it was revealed that “the commercialisation of kidneys is as common now as it was before the implementation of the Act and the present regulatory system is incapable of preventing it.” Trade in human organs have attained legal immunity due to the misuse of Section 9(3) of the Act which states that no human organ removed from the body of a donor before his death shall be transplanted unless a donor is a near relative of the recipient. However with the approval of the Authorisation Committee, the donor can allow transplantation to unrelated persons. The major

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323 Nagral: Deceased organ donation in India: where do we go from here? -Indian Journal of Medical Ethics Vol.11 No. 3 2014
326 Section 2(1) of THOA defines ‘Near Relative’ as spouse, son, daughter, father, mother, brother or sister.
drawback is that the Committee is not proffered by the donor or recipient with any means to verify the information provided by them. Often the inquiry held by the Committee as to whether the donor and the recipient have complied with all the requirements of the Act is cursory. A case was reported where a prospective recipient filed a writ petition before the High Court of Karnataka to get approval for receiving the kidney from the sister-in-law of the recipient on the ground that she was not a close relative. The High Court allowing the writ petition held as follows:

"There is no provision in the Act which prohibits the person who is not a 'near relative' by definition, from donating his kidney merely because the 'near relative' has not been considered as donors by the family for kidney transplantation. The Committee has misdirected itself in this regard while refusing permission to the petitioners." Further, "The Committee would ascertain from the second petitioner whether she would be donating the kidney out of 'affection and attachment'. The donors relationship with the recipient, period of acquaintance and the degree of association, reciprocity of feelings, gratitude and other human bonds are perhaps some of the factors which would sustain 'affection and attachment' between two individuals. The committee has to ensure that the human organ does not become an article of commerce. The main thrust of the Act is against commercial dealings in human organs."

The different interpretations to the Section and the law in force have created loopholes and at times created difficulties in conducting legal transplantations. Indulgence of middlemen for procurement of human organs from hospitals, marriage solemnised and separated solely for the purpose of organ transplant, receiving the approval of the Committee using proxy donor are a few instances that surpass legal regulation. It is highly impossible to regulate such nefarious activities in the presence of such ineffectual legislation. Further, while the Act permits the live donors to donate to unrelated recipients, it does not have any provision to protect the donors by providing financial support or a fine quality of post-operative treatment to them. A large number of institutions have still not recognised the non-transplant organ retrieval centres. Hence, prospective donors are often transferred to the hospitals which are legally recognised for transplantation. This is an obvious conflict of interest scenario as the hospital can then use the organs as it gets priority as an "in house" donor. The absence of a common registry and a central network to procure organs and identifying recipients has resulted in the failure of

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328 B.L. Nagaraj And Others vs Dr. Kantha And Others [AIR 1996 Kant 82]
successful transplantation of human organs. In the state of Tamil Nadu, however, the Government has taken initiative in 2008 through the TRANSTAN program which is “Transplant Authority of Tamil Nadu: Cadaver Transplant Programme” to regulate donation of human organs by providing donor card, wait-listing of the recipients and further furnishing annual reports and statistical performance data on organ donation 329.

Complexities in Organ Donation- A statistical study

Organ Donation in India appears to be business proposition- organ commerce for some and a solution for some. The prime cause for this scenario is the growing disparity between the rich and poor, the growth in middle class population, lack of national insurance scheme and a lack of post care protection for donors 330. An interesting field study on Economic and Health Consequences of Selling a Kidney in India was conducted and reported in 2002 and the results of the study still holds good. It was found that 96% of participants (over 300) sold their kidneys to pay off debts. The average amount received was $1070. Most of the money received was spent on debts, food, and clothing. The average family income declined by one-third after removal of the kidney (p<.001) and the number of participants living below the poverty line increased. A total of three-fourths of the participants were still in debt at the time of the survey. About 86% of participants reported deterioration in their health status after Nephrectomy. A total of 79% would not recommend that others sell a kidney. The article concluded that among the paid donors in India, selling a kidney does not lead to a long-term economic benefit and may be associated with a decline in health. Goyal, et al. concluded that: “In developing countries like India, potential donors need to be protected from being exploited. At a minimum, this might involve educating them about the likely outcomes of selling a kidney” 331.

The major complexity or difficulty in organ donation is identifying the donors and the recipients. As population is widely spread, the supplies cannot adequately meet the demands. The public awareness on organ donation is significantly lower and there is a fear imbibed even to pursue a noble cause in this commercial world. Several Non-Governmental organisations in India are trying to change the situation by promoting awareness on organ donations, encouraging citizens to lawfully donate their organs with a non-commercial motive. In the

329http://www.dmrhs.org/tnos/
State of Kerala which has a high literacy rate, a cross-sectional study was conducted on rural inhabitants above 18 years of age to assess their knowledge and attitude towards organ donation. The result was that 97% of the participants had heard about organ donation, however only 53% had a good knowledge. Nearly 48% had poor attitude regarding organ donors and around 50% believed organ donation to cause severe health problems. Organ specific willingness for donation was high among the participants for eye, followed by kidney and liver. Over 1,00,000 people develop end-stage kidney failure every year in India, but only 3% are blessed with a transplant.

There is an evident rise in the number of fatal road accidents and correspondingly dying of brain deaths. In 2010, nearly 1,33,938 died of accidents and 70% of such deaths were brain deaths. These accidents have increased to 4,51,757 in 2014. An increase of 12.8% was observed in accidental deaths in the country during 2014 over 2013. Similarly, the suicide rates have also increased significantly and now stands at 10.6%. Even if 5% to 10% of all these deceased patients became organ donors, it would mean that there would be no requirement for a living person to donate an organ. Promoting the cadaver donation program would not only help kidney transplants but also harvesting of other organs such as liver, heart, pancreas and lung transplants to thrive in the country. Promoting cadaver transplantation can encourage more organ donations in the country to meet the vital demands. Since 1994, there was little substantial activity in terms of declaration of brain death and donation after brain death. Even in the better performing regions of the country the deceased or cadaver renal transplantation rate is only 0.08 per million per year. As of 2014, 2,500 cadaver transplants have been performed in India, mainly in the last five years in the states of Tamil Nadu, Andhra Pradesh, Maharashtra, Kerala and Gujarat. Tamil Nadu and the city of Chennai in particular, have seen significant success in cadaver donation with around 4112 cadaver organs transplanted till date.

**Proposed Changes**

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334 Accidents and Suicide Deaths in India Report 2014: National Crime Records Bureau


336 *Organ Donation Promotion in India: A Critical Analysis*; International Journal of Health Sciences and Research Vol.4; Issue: 8; August 2014

337 http://www.dmrhs.org/tnos/reports/
The Transplantation of Human Organs Act, 1994 requires amendments to suit the need of the hour. The provisions of the Act are required to be made clear with respect to persons who can be donors and recipients of organs. The Act must be strictly interpreted in order to remove ambiguities to implement them effectively. The object of the Act must also extend to cover ethical concerns on organ transplantation. Further provisions may be incorporated to remove indulgence of middlemen by setting up bodies or centres for organ procurement, prosecution and punishment of such middlemen and also providing compensation to the victims of organ trade. The concerned State Governments and the Central Government may control such procurement centres by issuing orders and making policy rules to meet the dynamic needs of the society.

In a country like India with such huge population and vast demography, a successful transplantation system can be modelled only if it has a well-defined and resilient network proposed by the government and assisted by private and non-governmental organizations. The system should consist of a strong hierarchal network at both the state and the central levels. Each state must consist of a State Level Organ Procurement Agency which coordinates all transplantation activities in the state. The State Level Organ Procurement Agency shall have complete jurisdiction over the state in transplantation cases. The Organ Procurement Agency shall consist of transplant coordinators and organ donor coordinators. The hospitals that are involved in transplantation activities shall be recognized as transplant centres by the state and central governments. Such transplantation centres shall have highly qualified doctors and technicians specialised in transplantation filed of medical science. Such transplantation centres shall have a separate set up such as intensive care units exclusively for transplant patients and special surgical units for the transplant donors and recipients. At present as per the mandate of THOA Amendment in 2011, a nodal networking agency for procurement of organs and tissues for therapeutic purposes has been established in Delhi and also proposed to be extended to other parts of the country. In 2015-16, the union government allocated Ten Crore Rupees for Organ Transplant Scheme under the Ministry of Health and Family Welfare to develop an organized system for organ procurement and distribution.

At the central level, a Central Organ Procurement and Transplantation Agency must be set up. This agency should be headed by a technical expert committee which consists of expert doctors and transplant coordinators. Each State Level Organ Procurement Agency should be a part of

338 http://notto.nic.in/about-us.htm
the Central Organ Procurement and Transplant Agency. The most important aspect of the Central system is the establishment of a Central Registry. The registry should be made up of two sections. The first section called the Donor Registry should consist of a detailed list of organ donors, their contact details, their consent status, the organs that they have consented to donate and the technical details of these organs. The second section called the Recipient Registry should consist of a list of patients with organ failure waiting for the donor organs. This waiting list shall be prioritised by considering policies for allocation like medical status, patient status, time on waiting list, blood type, tissue type, height and weight and factors like age of the patient, family status and other incidental factors involving the patient’s habits like smoking and alcoholism may be considered.

Once an organ is available in case of brain or other deaths, the State Level Organ Procurement Agency has to be immediately notified. The State Level Organ Procurement Agency will immediately notify the Central Organ Procurement and Transplantation Agency. Upon such notification the donor’s name shall be checked on the registry. If the consent is already available, the agency can move on to the next step towards finding the suitable recipient. In case the prospective donor’s consent is not available on the Central Donor Registry, the family’s consent shall be obtained. Once the consent is obtained, the recipient shall be chosen from the recipient waitlist registry as per a mathematical algorithm that will match the donor’s organ to a suitable recipient. Ultimate priority shall be given to the recipients in the same geographical location or state as delay in transplantation procedures may cause a failure or rejection of the transplant organ by the recipient body. Where the donor is found to be unsuitable after organ harvesting, the harvested organ shall be stored in organ banks if possible and in cases where such storage is not possible, such harvested organs shall be used exclusively for transplant research purposes. The main objective of the Central Organ Procurement and Transplantation Agency must be to reduce or eliminate shortage of organs for transplantation, increase the number of donors by spreading awareness and ensure effective transplantation network within the country. Laws against organ trade and trafficking shall be made extremely stringent and more importantly, execution of these laws shall be highly proficient.

Creating awareness amongst public is a quintessential step to remove myths on organ donation. Mislead opinions and views on organ donation have discouraged people from donating their organs. Awareness on organ donation may be addressed at three levels:

a) Religious Awareness; b) Altruistic Awareness; c) Media Awareness. Every religion in the world encourages organ donation and is considered a noble act. Willingness to donate is
directly proportional to level of education on such donations, which needs to be increased. Religious institutions must attempt to propagate the noble act by emphasising the cause of living and the value for life. In the past, Gujarat has had considerable success with the eye donation program due to the large population of the Jain community in the state. This community considers eye donation as a sublime form of charity and believes in a powerful link between ‘daan’ (charity) and ‘moksha’ (salvation)\textsuperscript{340}. Creating altruistic awareness is an extended concept of religious awareness where people must be motivated to lead a selfless life by donating their organs to transform the lives of many others. It can be achieved by conducting sessions to teach or preach on what practically happens to the body of the donor on donation as it is most often misunderstood to create health hazards to the donor. Other social, physiological myths could be addressed by creating an altruistic awareness amongst the public. Media awareness is equally important as it is a powerful tool to reach the masses and if channelized in the right way can help promote the cause of organ donation.

**Transplant Tourism and Red Market Scams**

The shortage of organs for transplantation has caused organ trade to be a worldwide phenomenon. Organ trade can be defined as the trade of human organs for the purposes of transplantation. The Istanbul Declaration on Organ trafficking and transplant tourism was an International Summit convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey in 2008. It is a nonbinding declaration where over hundred countries endorsed its principles. The summit also had participants from India. The Istanbul Declaration on Organ trafficking and Transplant Tourism defines *Organ trafficking* as the recruitment, transport, transfer, harbouring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation. It also defines Transplant commercialism as a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.\textsuperscript{341} Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centres) devoted to

\textsuperscript{340}Legal and ethical aspects of organ donation and transplantation Indian J Urol. 2009 Jul-Sep; 25(3): 348–355

providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population. While organ trade is illegal in most of the countries in the world, the legal status is constantly evolving. A few countries have made organ donation legal while many other countries like Australia provide financial support to their live donors to reduce the financial burden for taking off from work and they also provide sickness benefits to the unemployed donors.

Iran is one of the countries in which organ trade was made legal by the ‘Gift of Altruism’/‘Rewarded Gifting’ governmental scheme by which any kidney donor was approved by the Board of Ministers in early 1997. The Scheme bans transplant tourism by denying transplantation to recipients without Iranian citizenship. As a result of this scheme, 48.5% of patients with end stage renal disease in Iran are living with a functioning graft currently. However, the undesirable consequence of this scheme cannot be brushed aside. Many reports have been released as to a phenomenon where the streets near the hospitals have turned into “kidney eBay”. The walls are adorned with the advertisements to sell kidneys. The blood group and contact details of willing donors have been posted. Most of the donors are from impoverished backgrounds. Those living below the poverty line, trapped in debt cycles and economically disadvantaged become the ideal donors as the prices of these organs are in a competitive market. The donors seek the highest possible price according to the demand and supply in the market and the rich can be transplanted.

The World Health Organization (WHO) in its statement on the sale of organs clearly states that it violates the Universal Declaration of Human Rights as well as its own constitution: “The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment… for organs should be prohibited.” The WHO advises physicians not to...
transplant organs “if they have reason to believe that the organs concerned have been the
subject of commercial transactions.” 346

The illegal nature of organ trafficking has led to a countless number of scams in the “Red
Market”. The term “Red market” was coined by investigative journalist Scott Carney. Since
body parts cannot be classified as commodities in the strict sense, the term “Red Market” was
coincided to mean the multi-billion dollar illegal trade of body, bones and body parts. The red
market organ trafficking has been seen in many countries. Many organised criminal groups are
involved in the organ trade scams. Those accused of being involved in such illegal organ trade
escape conviction many a times because of the absence of extensive, comprehensive and
stringent laws in their respective countries. As a result, those who have ravaged impoverished
human donors have been left scot free.

One such racket is the kidney theft scam in the state of Uttar Pradesh in India in 2008. A group
of doctors, paramedics, nurses, private hospitals, pathology clinics and diagnostic clinics were
alleged of running an illegal kidney theft circuit. Under-privileged day labourers and penurious
farmers in the labour market of the state were lured with profitable day wage in return to a
day’s labour. The victims were however unaware of the nature of work. The victims were then
abducted and then persuaded to sell their organs. They were also forced to undergo operations
for reasons unknown to them. After a raid by the Indian police in 2008, it was revealed that the
circuit had performed approximately six hundred illegal kidney transplants.347 The convicted
persons were subsequently released due to non availability of sufficient evidence.

Such rackets have also been reported in other countries. In 2002, the United Nations War
Crimes prosecutors investigated a case where ethnic Serbs of Kosovo were killed by
perpetrators and their organs were harvested for commercial purposes during the 1998-1999
Kosovo War. Many of the victims were civilians, combatants and even mental patients from
Serbia.348

348 “Were Kosovo patients slain for organs?” Associated Press. 2008-11-24 ,
http://www.nbcnews.com/id/27700612/ns/health-health_care/t/were-mental-patients-organ-trafficking-victims/#.VtHbt_l97VU
In China, reports of systematic organ harvesting have been released in 2006. It was alleged that tens of thousands of Falun Gong prisoners were killed to supply organs and cadavers for the organ trade prevalent in the country.349

In another case, poor people from Turkey, Moldova and Russia were persuaded to travel to Kosovo to donate organs in return for monetary considerations. Two dozen donors were taken in by the scheme; many were never given any compensation and were released without adequate medical care. Five people were convicted in 2013 in connection to this organ trafficking network.350

Such incidents have caused an air of apprehension in the minds of people. Illegal organ trafficking and transplant tourism can be curbed only if the numbers of organ donors are increased and the shortage of organs for donation is completely brought down. Addressing this issue of transplant tourism is the need of the hour.

Conclusion

Organ donation is one of the noblest forms of charity and the advancements in Medical Sciences have made organ transplantation a successful technique to save the lives of many. The deed of organ donation is however not popular amongst the public as it involves several ethical, social, cultural and psychological issues attached to it. Susceptible laws, variable interpretation of their provisions and their ineffective implementation have been a major cause for illegal organ trade and increase in commercialisation of organ transplantation. Lack of awareness amongst the public, lack of governmental participation in monitoring hospitals and institutions involved in the cause of organ transplantations, indulgence of middlemen for procurement of organs and tissues poses challenges to the effective implementation of the Act. The requirement to establish a centralised registry with a hierarchical setup can help curb illegal organ trade as well as face organ shortage problems. Transplant tourism and organ trafficking are international threats which are likely to affect people in developing countries. Hence the law needs to be reformed according to the dynamic needs of the society to promote and conduct legal organ transplantations.